

Message Text

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63

ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 ISO-00 OES-05 /034 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.: AMS

APPROVED BY OES/APT/BMP: WJWALSH, III

DHEW/OIH: MACODDING

ARA/EX:KDACKERMAN(INFO)

----- 097507

P 022244Z MAR 76

FM SECSTATE WASHDC

TO AMEMBASSY SANTIAGO PRIORITY

AMEMBASSY SAN JOSE PRIORITY

AMEMBASSY SANTO DOMINGO PRIORITY

AMEMBASSY SAN SALVADOR PRIORITY

AMEMBASSY GUATEMALA PRIORITY

AMEMBASSY TEGUCIGALPA PRIORITY

AMEMBASSY MANAGUA PRIORITY

AMEMBASSY LIMA PRIORITY

AMEMBASSY MONTEVIDEO PRIORITY

AMEMBASSY CARACAS PRIORITY

AMCONSUL HAMILTON PRIORITY

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E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, BD, CI, CS, DR, ES, GT,
HO, NU, PE, UY, VE

SUBJECT: FDA ADVISORY - FAULTY MANUFACTURING PRACTICES
AND POSSIBLE PRODUCT NON-STERILITY (RECALL NO. D-205-6)

1. FDA ADVISES THAT:

PRODUCT INVOLVED:

(A) CARBOCAINE HCL 3 PERCENT (BRAND OF MEPIVACAINE);
COOK-WAITE LABORATORIES, INC., NY, NY 10016 (DISTRIBUTOR);
INJECTABLE

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50/1.8 ML CARTRIDGES PER CAN AND
50/20 ML VIALS PER BOX.

(B) CARBOCAINE 3 PERCENT (MEPIVACAINA); WINTHROP PRODUCTS,
INC., NUEVA YORK, N.Y. 10016; INJECTABLE 50/1.8 ML
CARTRIDGES PER CAN.

LOT NUMBERS:

THESE PRODUCTS HAVE LOT NUMBERS CONSISTING OF THREE LETTERS
FOLLOWED BY 2 DIGITS. ALL LOTS OF CARTRIDGES WITH AN "L"
IN THE SECOND POSITION ARE BEING RECALLED. ALSO, ALL LOTS

WITH THE FOLLOWING COMBINATIONS IN THE FIRST TWO POSITIONS
ARE BEING RECALLED: AN, CN, LN, RN, PN, UN. THE LOTS
OF 20 ML. VIALS BEING RECALLED ARE OLC 80 AND NLC80.

DISTRIBUTION: FROM 1/1/74 UNTIL 8/18/75

MANUFACTURER:

STERLING DRUG, INC.
33 RIVERSIDE AVENUE
RENSSELAER, NY 12144

RECALLING FIRM:

A.
COOK-WAITE LABORATORIES, INC.
90 PARK AVENUE
NY, NY 10016

B.
WINTHROP PRODUCTS
90 PARK AVENUE
NY, NY 10016

REASON FOR ADVISORY (RECALL)

THROUGH VARIOUS INSPECTION REPORTS AND AT CONFERENCES
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HELD WITH THE CORPORATION'S RESPONSIBLE OFFICIALS, FDA
ALLEGED THAT THE PRODUCTS WERE NOT AND HAD NOT BEEN
MANUFACTURED IN CONFORMANCE WITH CURRENT GOOD MANU-
FACTURING PRACTICE REGULATIONS AND THAT THERE WAS A
QUESTION OF PRODUCT STERILITY. AFTER SEVERAL MORE
MEETINGS AND IN-DEPTH REVIEWS OF BATCH RECORDS OF
"STERILE" DRUG PRODUCTS, THE FIRM INSTITUTED A RECALL OF
THE INJECTABLE PRODUCTS INVOLVED.

2. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE BEEN INFORMED OF THE DETAILS OF THE RECALL AND IF THEY HAVE RECEIVED THE RCA GLOBAL CABLES SENT BY THE FIRM TO ALL FOREIGN DISTRIBUTORS ON AN INDIVIDUAL BASIS CONCERNING THIS RECALL. POSTS MAY ALSO WISH TO CONTACT HOST COUNTRY DRUG CONTROL AUTHORITIES INFORMING THEM OF THE RECALL SO THAT THEY MAY TAKE SUCH ACTIONS AS THEY DEEM APPROPRIATE.

3. FOREIGN CONSIGNEES AS FOLLOWS:

1. BERMUDA GENERAL AGENCY, HAMILTON BERMUDA
2. THE SYDNEY ROSS CO. Y CIA (LTDA), SANTIAGO, CHILE
3. STERLING PRODUCTS INTERNATIONAL S. A., SAN JOSE, COSTA RICA
4. STERLING PRODUCTS INTERNATIONAL, INC., SANTO DOMINGO, DOMINICAN REPUBLIC
5. CENTRAL AMERICA ADMINISTRATION, STERLING PRODUCTS INTERNATIONAL, INC. C.A.A. SAN SALVADOR, EL SALVADOR, C.A.
6. STERLING PRODUCTS INTERNATIONAL S.A., GUATEMALA CITY, GUATEMALA
7. STERLING PRODUCTS INTERNATIONAL S.A., TEGUCIGALPA, CD.C., HONDURAS
8. LABORATORIOS FARMACEUTICOS DE NICARAGUA, S. A. MANAGUA, NICARAGUA
9. SYDNEY ROSS, S. A., LIMA, PERU
10. SYDNEY ROSS URUGUAY LIMITADA, MONTEVIDEO, URUGUAY
11. THE SYDNEY ROSS CO., CARACAS, VENEZUELA INGERSOLL

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Disposition Approved on Date:
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Disposition Event:
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Drafter: JRWEINROTH, M.D.: AMS
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Margaret P. Grafeld
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EO Systematic Review
04 MAY 2006

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